Complete Summary

GUIDELINE TITLE

Practice advisory for the perioperative management of patients with cardiac rhythm management devices: pacemakers and implantable cardioverter-defibrillators: a report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Cardiac Rhythm Management Devices.

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force, Perioperative Management of Patients with Cardiac Rhythm Management Devices. Practice advisory for the perioperative management of patients with cardiac rhythm management devices: pacemakers and implantable cardioverter-defibrillators: a report by the ASA Task Force on perioperative management of patients with cardiac rhythm. Anesthesiology 2005 Jul;103(1):186-98. [81 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Any condition that requires anesthesia for surgical procedures in a patient with a permanently implanted cardiac rhythm management device (CRMD) for treatment of bradyarrhythmia, tachyarrhythmia or heart failure

GUIDELINE CATEGORY

Evaluation
Management

CLINICAL SPECIALTY

Anesthesiology
Cardiology
Internal Medicine
Radiology
Thoracic Surgery

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

To: (1) facilitate safe and effective perioperative management of the patient with a cardiac rhythm management device (CRMD), and (2) reduce the incidence of adverse outcomes

Note: Perioperative management refers to the preoperative, intraoperative, postoperative or recovery period in any setting where an anesthesia provider will be delivering anesthesia care.

TARGET POPULATION

All patients requiring anesthesia for a surgical procedure who have a pre-existing, permanently implanted cardiac rhythm management device (CRMD) for treatment of bradyarrhythmia, tachyarrhythmia or heart failure

Note: Both inpatient and outpatient procedures are addressed by this Advisory. This Advisory does not address the perioperative management of any patient undergoing CRMD implantation or revision. It is not applicable to any patient: (1) without a permanently implanted pacemaker or implantable cardioverter-defibrillator (ICD), (2) with a temporary CRMD, (3) with a noncardiac implantable device (e.g., neurological or spinal cord stimulator), or (4) with an implantable mechanical cardiac assist device (e.g., ventricular assist device). This Advisory does not address any procedure where there are no known perioperative CRMD concerns, such as diagnostic radiation (e.g., x-rays, fluoroscopy or mammograms), computed tomography scans, or ultrasound.

INTERVENTIONS AND PRACTICES CONSIDERED

Preoperative Evaluation

1. Establishing whether patient has a cardiac rhythm management device (CRMD)
2. Defining the type of CRMD (manufacturer's ID, supplemental resources)
3. Determining dependency on pacing function of the CRMD
4. Determining CRMD function

Preoperative Preparation

1. Determining if electromagnetic interference (EMI) is likely to occur during the procedure
2. Determining whether reprogramming pacing function to asynchronous mode or disabling rate responsive function is advantageous
3. Suspending anti-tachyarrhythmia functions (if present)
4. Advising individual performing the procedure to consider use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel
5. Assuring immediate availability of temporary pacing and defibrillation equipment
6. Evaluating possible effects of anesthetic techniques and procedure on CRMD function

Intraoperative Management

1. Electrocardiograph (ECG) monitoring per American Society for Anesthesiologists (ASA) standard
2. Continuous peripheral pulse monitoring
3. Management of potential CRMD dysfunction due to electromagnetic interference (EMI) during:
    - Electrocautery
    - Radio-frequency (RF) ablation
    - Lithotripsy
    - Magnetic resonance imaging
    - Radiation therapy
    - Electroconvulsive therapy
4. Emergency defibrillation or cardioversion

Postoperative Management

1. Monitoring (cardiac rate and rhythm, availability of back-up pacing and defibrillation equipment)
2. Interrogating and restoring CRMD function

MAJOR OUTCOMES CONSIDERED

- Length of hospital stay
- Delay or cancellation of surgery
- Cardiac rhythm management device (CRMD) malfunction
- Incidence of adverse outcomes
- Re-hospitalization rate

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For this Advisory, a literature review was used in combination with opinions obtained from experts and other sources (e.g., professional society members, open forums, Web-based postings) to provide guidance to practitioners regarding the perioperative management of patients with cardiac rhythm management devices (CRMDs). Both the literature review and opinion data were based on *evidence linkages*, consisting of directional statements about relationships between specific perioperative management activities and CRMD function or clinical outcomes.

A study or report that appears in the published literature is included in the development of an advisory if the study: (1) is related to one of the specified linkage statements, (2) reports a finding or set of findings that can be tallied or measured (e.g., articles that contain only opinion are not included), and (3) is the product of an original investigation or report (i.e., review articles or follow-up studies that summarize previous findings are not included). Since CRMDs represent a rapidly changing technology, earlier literature (i.e., literature published before 1990) was rarely included in the evaluation of evidence for this Practice Advisory.

Although evidence linkages are designed to assess causality, few of the reviewed studies exhibited sufficiently acceptable quantitative methods and analyses to provide a clear indication of causality. Therefore, the published literature could not be used as a source of quantitative support (required for the development of practice guidelines). However, many published studies were evaluated that provided the Task Force with important non-causal evidence. For example, descriptive literature (i.e., reports of frequency or incidence) is often useful in providing an indication of the scope of a problem. Information regarding whether a particular adverse outcome is common or rare may have considerable bearing on the practicality of an advisory. Case reports are typically employed as a forum for reporting and recognizing unusual or adverse outcomes, and may suggest caution when devising an advisory.

For the literature review, potentially relevant studies were identified via electronic and manual searches of the literature. The electronic search covered a 39-year period from 1966 through 2004. The manual search covered a 44-year period of time from 1961 through 2004. Over 1,500 citations were initially identified, yielding a total of 411 non-overlapping articles that addressed topics related to the evidence linkages. Following review of the articles, 283 studies did not provide direct evidence, and were subsequently eliminated. A total of 128 articles (from 39 journals) contained direct linkage-related evidence.

NUMBER OF SOURCE DOCUMENTS

A total of 128 articles (from 39 journals) contained direct linkage-related evidence.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Literature Review

Inter-observer agreement among Task Force members and two methodologists was established by inter-rater reliability testing. Agreement levels using a kappa statistic for two-rater agreement pairs were as follows: (1) type of study design, kappa = 0.72 to 0.90; (2) type of analysis, kappa = 0.80 to 0.90; (3) evidence linkage assignment, kappa = 0.84 to 1.00; and (4) literature inclusion for database, kappa = 0.70 to 1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.81, Var (Sav) = 0.010; (2) type of analysis, Sav = 0.86, Var (Sav) = 0.009; (3) linkage assignment, Sav = 0.82 Var (Sav) = 0.005; (4) literature database inclusion, Sav = 0.78 Var (Sav) = 0.031. These values represent moderate-to-high levels of agreement.

Consensus-Based Evidence

Consensus was obtained from multiple sources, including: (1) survey opinion from Consultants who were selected based on their knowledge or expertise in perioperative management of cardiac rhythm management devices (CRMDs), (2) survey opinions from randomly selected samples of active members of the American Society of Anesthesiologists (ASA) and active members of the Heart Rhythm Society (HRS), (3) testimony from attendees of two publicly-held open forums at a national anesthesia meeting and at a major cardiology meeting, (4) internet commentary, and (5) Task Force opinion and interpretation. The survey rate of return was 56% (N = 23/41) for Consultants, and 15% (N = 89/600) for the ASA membership, and 15% (N = 44/300) for the HRS membership (see Table 1 of the original guideline document).

The ASA Consultants were asked to indicate which, if any, of the evidence linkages would change their clinical practices if the Advisory was instituted. The rate of return was 37% (N = 15/41). The percent of responding Consultants expecting no change associated with each linkage were as follows: preoperative evaluation - 71%; preoperative patient preparation- 71; intraoperative monitoring of CRMDs - 64%; emergency defibrillation or cardioversion - 86%; postoperative monitoring of CRMDs - 79%; postoperative interrogation and restoration of CRMD function - 64%; intraoperative management of electromagnetic interference (EMI) during: electrocautery - 79%; radio-frequency ablation - 79%, lithotripsy - 79%, MRI - 79%, radiation therapy - 86%, and electroconvulsive therapy - 79%. Forty-three percent of the respondents indicated that the Advisory would have no effect on the amount of time spent on a typical case. Eight respondents (57%) indicated that there would be an increase in the amount of time they would spend on a typical case with the implementation of this Advisory. The amount of increased time anticipated by these respondents ranged from 5-30 minutes.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society of Anesthesiologists (ASA) appointed a Task Force of 12 members to: (1) review and assess currently available scientific literature; and (2) obtain expert consensus and public opinion, and (3) develop a practice advisory. The Task Force members consisted of anesthesiologists and cardiologists in private and academic practices from various geographic areas of the United States, and two methodologists from the ASA Committee on Practice Parameters.

The Task Force used a six-step process. First, they reached consensus on the criteria for evidence of effective perioperative management of cardiac rhythm management devices. Second, original published articles from peer-reviewed journals relevant to these issues were evaluated. Third, consultants who had expertise or interest in cardiac rhythm management devices (CRMDs), and who practiced or worked in various settings (e.g., academic and private practice) were asked to: (1) participate in opinion surveys on the effectiveness of various perioperative management strategies, and (2) review and comment on a draft of the Advisory developed by the Task Force. Fourth, opinions about the Advisory statements were solicited from random samples of active members of both the ASA and the Heart Rhythm Society (HRS). Fifth, the Task Force held an open forum at a national anesthesia meeting and at a major cardiology meeting to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document was made available for review on the American Society of Anesthesiologists (ASA) Web site, and input was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

A summary of the Practice Advisory is presented below.

Preoperative Evaluation

- Establish whether a patient has a cardiac rhythm management device (CRMD).
    - Conduct a focused history (patient interview, medical records review, review of available chest x-rays, electrocardiogram [ECG] or any available monitor or rhythm strip information).
    - Conduct a focused physical examination (check for scars, palpate for device).
- Define the type of CRMD.
    - Obtain manufacturer's ID card from patient or other source.
    - Order chest x-ray if no other data are available.
    - Refer to supplemental resources (e.g., manufacturer's databases).
- Determine dependency on pacing function of the CRMD.
    - History of symptomatic bradyarrhythmia resulting in CRMD implantation
    - History of successful atrioventricular (A-V) nodal ablation
    - Inadequate escape rhythm at lowest programmable pacing rate
- Determine CRMD function.
    - Interrogate device (consultation with a cardiologist or pacemaker-implantable cardioverter-defibrillator (ICD) service may be necessary).
    - Determine whether the device will capture when it paces (i.e., produce a mechanical systole with a pacemaker impulse).
    - Consider contacting the manufacturer for perioperative recommendations.

Preoperative Preparation

- Determine if electromagnetic interference (EMI) is likely to occur during the planned procedure.
- Determine whether reprogramming pacing function to asynchronous mode or disabling rate responsive function is advantageous.
- Suspend anti-tachyarrhythmia functions if present.
- Advise individual performing the procedure to consider use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel.
- Temporary pacing and defibrillation equipment should be immediately available.
- Evaluate the possible effects of anesthetic techniques and of the procedure on CRMD function and patient CRMD interactions.

Intraoperative Management

- Monitor operation of the CRMD.
    - Conduct ECG monitoring per American Society for Anesthesiologists (ASA) standard.

- Monitor peripheral pulse (e.g., manual pulse palpation, pulse oximeter plethysmogram, arterial line).
- Manage potential CRMD dysfunction due to EMI.
  - Electrocautery
    - Assure that the electrosurgical receiving plate is positioned so that the current pathway does not pass through or near the CRMD system. For some cases, the receiving plate might need to be placed on a site different from the thigh (e.g., the superior posterior aspect of the shoulder contralateral to the generator position for a head and neck case).
    - Advise individual performing the procedure to avoid proximity of the cautery's electrical field to the pulse generator or leads.
    - Advise individual performing the procedure to use short, intermittent, and irregular bursts at the lowest feasible energy levels.
    - Advise individual performing the procedure to reconsider the use of a bipolar electrocautery system or ultrasonic (harmonic) scalpel in place of a monopolar electrocautery system, if possible.
  - Radio-frequency (RF) ablation
    - Advise individual performing the procedure to avoid direct contact between the ablation catheter and the pulse generator and leads.
    - Advise individual performing the procedure to keep the RF's current path as far away from the pulse generator and lead system as possible.
  - Lithotripsy
    - Advise individual performing the procedure to avoid focusing the lithotripsy beam near the pulse generator.
    - If the lithotripsy system triggers on the R-wave, consider preoperative disabling of atrial pacing.
  - Magnetic resonance imaging (MRI)
    - MRI is generally contraindicated in patients with CRMDs.
    - If MRI must be performed, consult with the ordering physician, the patient's cardiologist, the diagnostic radiologist, and the CRMD manufacturer.
  - Radiation therapy
    - Radiation therapy can be safely performed in patients who have CRMDs.
    - Surgically relocate the CRMD if the device will be in the field of radiation.
  - Electroconvulsive therapy
    - Consult with the ordering physician, the patient's cardiologist, a CRMD service, or the CRMD manufacturer.
- Emergency defibrillation or cardioversion.
  - For the patient with an ICD and magnet-disabled therapies:
    - Advise individual performing the procedure to terminate all sources of EMI while magnet is removed.
    - Remove the magnet to re-enable antitachycardia therapies.
    - Observe the patient and the monitors for appropriate CRMD therapy.
    - If the above activities fail to restore ICD function, proceed with emergency external defibrillation or cardioversion.

- For the patient with an ICD and programming-disabled therapies:
    - Advise individual performing the procedure to terminate all sources of EMI while magnet is removed.
    - Re-enable therapies through programming if the programmer is immediately available and ready to be used.
    - Observe the patient and the monitors for appropriate CRMD therapy.
    - If the above activities fail to restore ICD function, proceed with emergency external defibrillation or cardioversion.
- For external defibrillation:
    - Position defibrillation/cardioversion pads or paddles as far as possible from the pulse generator.
    - Position defibrillation/cardioversion pads or paddles perpendicular to the major axis of the CRMD to the extent possible by placing them in an anterior-posterior location.
    - If it is technically impossible to place the pads or paddles in locations that help to protect the CRMD, then defibrillate/cardiovert the patient in the quickest possible way and be prepared to provide pacing through other routes.
    - Use a clinically appropriate energy output.

Postoperative Management

- Continuously monitor cardiac rate and rhythm and have back-up pacing and defibrillation equipment immediately available throughout the immediate postoperative period.
- Interrogate and restore CRMD function in the immediate postoperative period.
    - Interrogate CRMD; consultation with a cardiologist or pacemaker-ICD service may be necessary.
    - Restore all anti-tachyarrhythmic therapies in ICDs.
    - Assure that all other settings of the CRMD are appropriate.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The advisory statements contained in this document represent a consensus of the current spectrum of clinical opinion and literature-based findings.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduction in the incidence of adverse outcomes associated with a cardiac rhythm management device (CRMD) include (but are not limited to) damage to the device, inability of the device to deliver pacing or shocks, lead-tissue

interface damage, changes in pacing behavior, electrical reset to the backup pacing mode, or inappropriate cardioverter-defibrillator (ICD) therapies.
- Reduction in the incidence of adverse clinical outcomes include (but are not limited to) hypotension, tachyarrhythmia or bradyarrhythmia, myocardial tissue damage, and myocardial ischemia or infarction, extended hospital stay, delay or cancellation of surgery, readmission to manage device malfunction, or additional hospital resource utilization and cost.

POTENTIAL HARMS

Not stated

CONTRAINDICATIONS

CONTRAINDICATIONS

The Task Force believes that magnetic resonance imaging (MRI) is generally contraindicated for cardiac rhythm management device (CRMD) patients. If MRI must be performed, consult with the ordering physician, the patient's pacemaker specialist or cardiologist, the diagnostic radiologist, and the CRMD manufacturer.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Practice advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Advisories are not intended as standards, guidelines, or absolute requirements. They may be adopted, modified, or rejected according to clinical needs and constraints.
- The use of practice advisories cannot guarantee any specific outcome. Practice advisories summarize the state of the literature and report opinions derived from a synthesis of task force members, expert consultants, open forums, and public commentary. Practice advisories are not supported by scientific literature to the same degree as standards or guidelines because of the lack of sufficient numbers of adequately controlled studies. Practice advisories are subject to periodic revision as warranted by the evolution of medical knowledge, technology, and practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force, Perioperative Management of Patients with Cardiac Rhythm Management Devices. Practice advisory for the perioperative management of patients with cardiac rhythm management devices: pacemakers and implantable cardioverter-defibrillators: a report by the ASA Task Force on perioperative management of patients with cardiac rhythm. Anesthesiology 2005 Jul;103(1):186-98. [81 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Jul

GUIDELINE DEVELOPER(S)

American Society of Anesthesiologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Anesthesiologists

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Anesthesiologists Web site.

Print copies: Available from the American Society for Anesthesiologists, 520 North Northwest Highway, Park Ridge, IL 60068-2573.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 14, 2005. The information was verified by the guideline developer on July 20, 2005.

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